

**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks made herewith, which place the application in condition for allowance, or in better condition for appeal. Examiner Switzer is thanked for courtesies extended during the telephonic interview of August 30, 2004.

Pursuant to the provisions of 37 C.F.R. §§ 1.17(a) and 1.136(a), Applicants petition the Assistant Commissioner to extend the time period for Applicants to respond to the outstanding Office Action by two (2) months, i.e., up to and including October 14, 2004. A check for \$215.00 is enclosed with this Amendment. Applicants hereby authorize the Assistant Commissioner to charge any additional fee for consideration of this amendment, or credit any overpayment, to Deposit Account No. 50-0320.

**I. Status of the Claims and Formal Matters**

Claims 52-65 and 67-81 are pending in this application. By this paper, claims 52-81 are cancelled, without prejudice. New claims 82-94 have been added.

These amendments have been made simply for clarification and to place the claims in condition for allowance. No new matter has been added by these amendments. Support for the amendments and new claims can be found throughout the specification. The amendments presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

The Examiner has objected to Claim 69 for allegedly containing the recitation of SEQ ID NO:5, which was withdrawn as a non-elected species. Claim 69 has been cancelled, without prejudice. Therefore, Applicants respectfully request that the Examiner's objection be withdrawn.

**II. Rejections under 35 U.S.C. §112, 1<sup>st</sup> Paragraph**

Claims 52-65 and 67-81 were rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph for allegedly failing to comply with the written description requirement. The Examiner contends that the claims contain subject matter that was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner has rejected the claims based upon the limitation of “to not hybridize to and/or amplify RNA or DNA of non-*Staphylococcus aureus* bacterial species” in claims 52, 53, 54, 58, 67, 68, and 69. Claims 52, 53, 54, 58, 67, 68, and 69 have been cancelled, without prejudice nor admission.

The Examiner has also rejected claims 70-81 for allegedly adding new matter, specifically the addition of positive and negative control nucleic acids to the kits of the present invention. Likewise, claims 70-81 have been cancelled, thereby rendering the rejection moot.

In the telephonic interview of August 30, 2004, Examiner Switzer suggested amending the claims to indicate a probe “consisting of” a particular SEQ ID NO. New claims 82-94 now recite the term “consisting of”, rendering the rejections under 35 U.S.C. §§102(a) and 112 1<sup>st</sup> paragraph moot. Therefore, in view of the foregoing, reconsideration and withdrawal of the rejections are respectfully requested.

### **III. Rejections under 35 U.S.C. §102(b)**

Claims 52-63 and 67-69 were rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Kunsch et al (Canadian Patent Application no. 2194411). The Examiner argues that Kunsch anticipates the instant invention by teaching kits comprising at least one nucleic acid probe, wherein at least one of the nucleic acid molecules hybridizes selectively to the RNA or DNA of *Staphylococcus aureus*. This rejection is respectfully traversed in view of the amendments to the claims and the Declaration provided by Dr. Kornelia Berghof-Jaeger, submitted herewith.

Kunsch describes 5,191 nucleic acid sequences that, in sum, correspond to the primary nucleotide sequence of the *S. aureus* genome, but fail to indicate which sequences are specific for *S. aureus*. The *S. aureus* genome comprises regions that are highly variable, and presumably contain sequences that are not specific for *Staphylococcus aureus*. The skilled artisan, seeking to identify sequences that are specific for *S. aureus*, would have been required to perform an undue number of experiments to determine suitable sequences from the large and unmanageable number of nucleic acid sequences disclosed in Kunsch.

The Declaration of Dr. Kornelia Berghof-Jaeger states that the teachings of Kunsch, which disclose a large number of sequences corresponding to the sequence of the *S. aureus* genome, do not provide any specific teaching as to which fragments or which nucleotide positions in the large bacterial genome would be suitable in the present invention. Each and every one of the 5,191 sequences taught by Kunsch would need to be tested to determine their usefulness and specificity before including the nucleic acid primers and probes in a kit designed to rapidly and reliably measure the presence of *S. aureus* without cross-reactivity or cross-hybridization to non-*S. aureus*-specific sequences. Further, the instant specification clearly indicates "detection based on differential DNA sequences requires very comprehensive preliminary work in order to find suitable DNA sequences having the desired specificity in each case" (page 3 of the specification, third paragraph).

In the Declaration, Dr. Berghof-Jaeger compares Kunsch to the Human Genome Project, which has sequenced the entire human genome. However, the enormous number of sequences afforded by the Project does not present the skilled artisan with sequences that are specific and suitable for use in, for example, identifying genes that are involved in diseases for which the causes are unknown. It would be counterproductive and overly burdensome to test every single sequence in the human genome to determine the gene or gene families involved in the etiology of a disease. Similarly, the number of sequences taught by Kunsch would have to be individually tested and modified before their inclusion in diagnostic kits that rapidly and specifically detect *S. aureus* as described by the instant invention. Consequently, reconsideration and withdrawal of the §102(b) rejection is respectfully requested.

#### **IV. Rejections under 35 U.S.C. §103(a)**

Claims 64-65 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Kunsch in view of Buchardt et al (Trends in Biotechnology (1993) 11(9): 384-386). The Examiner contends that it would have been obvious to one of skill in the art to modify the detection fragment taught by Kunsch to use PNAs instead of DNA as a detection fragment.

The Declaration of Dr. Kornelia Berghof-Jaeger states that it would not have been advantageous to combine the teachings of Kunsch and Buchardt. Kunsch describes 5,191 sequences corresponding to the *S. aureus* genome. The skilled artisan would not have been motivated to individually test *and* modify each and every one of the sequences disclosed in

Kunsch to determine which peptide nucleic acids that are specific for *S. aureus*. This would constitute an undue burden on the skilled artisan to determine which sequences are suitable for inclusion into, for example, diagnostic kits useful in detecting *S. aureus* strains rapidly and reliably. A skilled artisan would not have been motivated to use PNAs in sequences disclosed by Kunsch, since Kunsch fails to direct the skilled artisan to which sequences are actually useful for modification. It would be much simpler to determine a structure that is bacteria-specific and to find a sequence that is highly conserved between all species of *S. aureus* than to individually pick and choose sequences from the 5,191 sequences disclosed by Kunsch. Indeed, the present inventors have identified a sequence corresponding to the 23S/5S intergenic region of the bacterial ribosome, which, as a whole, exhibits a unique organization of rDNA interspersed by hypervariable intergenic regions (see specification, page 4, 2<sup>nd</sup> paragraph). The nucleic acid sequences encoding the prokaryotic ribosomal unit can contain repeats that vary in divergent species of bacteria.

Claims 70-81 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Kunsch in view of both Bergeron et al (U.S. Patent No. 5,994,066) and Shah et al (U.S. Patent No. 5,370,992). By this paper, Claims 70-81 have been cancelled, without prejudice, rendering this rejection moot.

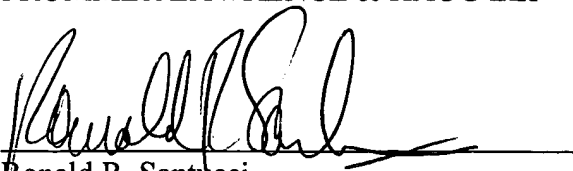
Therefore, reconsideration and withdrawal of the rejections under §103(a) are respectfully requested.

### CONCLUSION

In view of the foregoing amendments, it is believed that the claims in this application are patentable, and early and favorable consideration thereof is earnestly solicited.

Respectfully submitted,  
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